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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,238	10/29/2001	Yoram Eshel	U 013685-1	1243

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EXAMINER

LAMPRECHT, JOEL

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/021,238	Applicant(s) ESHEL ET AL.	
	Examiner Joel M. Lamprecht	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43,99-143,199 and 200 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43,99-143,199 and 200 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The Applicants' arguments have been considered but they are not persuasive. With regards to the amendments to "selectively lyse at least most of said adipose tissue in said target volume and generally not lysing non-adipose tissue in said target volume. With respect to the argument that the reference by Cribbs does not teach lysing cells by tissue type the Examiner would like to draw attention to Col 3 Lines 4-12 of the primary reference by Cribbs et al, which states that the focal zones can be adjusted to allow certain tissues to remain rather than simply destroying the entire layer of tissue. The argument that this somehow does not read on the selective lysing of at least most of the adipose tissue and generally not lysing the non-adipose tissue is respectfully traversed, as the aforementioned paragraph clearly points out that the Cribbs et al. reference is using focal regions to target specific types of tissues, leaving some after the procedure and removing others from the body. The use of the word matrix suggests, as is common in anatomy, the origins of a tissue or formative structure therein. Thus Cribbs et al. disclose a method for removing or lysing at least most of the adipose tissue in a target volume and generally not lysing non-adipose tissue in the target volume.

Claim Objections

1. Claim 1 is objected to because of the following informalities: It appears Applicants have misspelled lysing as "lysinge". The Examiner has currently interpreted

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the claim to read, "generally not lysing non-adipose tissue in said target volume".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. 5. Claims 1-11, 16, 17, 44-54, 101-111, 116, 117, and 144-154 are rejected under 35 U.S.C. 102(b) as being anticipated by Cribbs, et al (US 6071239). Cribbs discloses a method for lipolytic therapy using ultrasound energy in which fat cells, i.e. adipose tissue, is non-invasively destroyed (abstract). The HIFU is concentrated to kill cells lying in the focal zone (Col 2, Lines 18-21) so that it does not significantly damage cells outside the focal zone using an ultrasonic array on the skin surface that is focused on the target volume (Col 1, Lines 60-62). Both the gain and the intensity are dynamically changed, or modulated, by a microprocessor (Col 4, Lines 44-46 and Col 5, Lines 56). Imaging is used to "monitor tissue destruction during the lipolytic therapy" (Col 6, Lines 40-41). The focus may be varied by adjustment of the dimensions of the focal zones (Col 2, Lines 62-64) as well as the axial dimension of the focal zone (Col 2, Line 39). It is inherent in the fact that if the dimensions of the focal zones are changed, the volumes will change as well.

Claim Rejections - 35 USC § 103

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12-15, 18-24, 30-37, 43, 55-65, 71-78, 84, 112-115, 118-124, 130-137, 143, 155-165, 171-178, and 184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cribbs in view of Friedman, et al (US 6645162). Cribbs, as discussed above, discloses a method for lysing adipose tissue, however fails to explicitly disclose sensing cavitations at target volume and ultrasonic energy, as well as the frequency range and duty cycle used in modulation over time. Friedman also discloses using focused ultrasound to remove adipose cells within a subcutaneous tissue region. Friedman teaches that ultrasonic energy should be applied using a relatively low duty cycle, for example of about "twenty percent or less, preferably ten percent or less, and more preferably about one percent or less" (Col 3, Lines 5-8). Also, the frequency range used is between 0.25 and 30 megahertz (claim 2), which is between 250 KHZ and 30000 KHz. The transducer may also include detectors for sensing cavitations (abstract) occurring at the focal zone. This sensor may be a "cavitation strip detector", which is on the transducer, which is therefore detecting ultrasonic energy coupling to the external surface of the body. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Cribbs with the teachings of the reference by Friedman and use the frequencies, duty cycle, and sensors disclosed, as the specific frequency range and duty cycles used were chosen

specifically to reduce trauma to surrounding tissue, which is the goal of the method disclosed by Cribbs.

5. In addition, using a sensor to monitor cavitations would be advantageous for the same reason, as the device disclosed by Friedman "may minimize damage, such as that caused by... heating of neighboring tissues when unfocused ultrasound is indiscriminately introduced into a tissue region" (Col 2, Lines 53-56). Cribbs teaches all the method steps as set forth above. The apparatus concerning the structure of the lysing adipose tissue device are considered inherently taught by the disclosure.

6. Claims 25-27, 38-40, 66-68, 70, 79-81, 83, 125-127, 138-140, 166-168, 170, 179-181, and 183 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cribbs in view of Dory, et al (US 511 1822). Cribbs, as discussed above, discloses a method for lysing adipose tissue, however fails to explicitly disclose the number of cycles used. Dory teaches delivering 256 pulses during each of the successive time intervals (Col 3, Line 17) in which the ultrasound transducer generates an ultrasonic beam (Col 3, Line 51-52) focused on a target area. Cribbs and Dory teach all the method steps as set forth above.

7. The apparatus concerning the structure of the lysing adipose tissue device are considered inherently taught by the disclosure. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Cribbs in view of the teachings of Dory, as the pulse sequence prescribed by Dory improves the "quality of the echographic image, either of the zone to be treated or of the focal region"

(Col 2, Lines 1-5). A better quality image will allow more accurate planning and more precise removal of only adipose tissue and not other undesired tissues.

8. Claims 28, 29, 41, 42, 69, 82, 128, 129, 141, 142, 169, and 182 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cribbs in view of Friedman as Claims 28, 29, 41, 42, 69, 82, 128, 129, 141, 142, 169, and 182 are rejected applied to claims 20, 24, 33, 37, 60, 74, 120, 124, 133, 137, 160, and 174 respectively, above, and further in view of Dory. Cribbs and Friedman, both discussed above, disclose methods for lysing adipose tissue, but however fail to explicitly disclose the number of cycles used. Dory teaches delivering 256 pulses during each of the successive time intervals (Col 3, Line 17) in which the ultrasound transducer generates an ultrasonic beam (Col 3, Line 51-52) focused on a target area. Cribbs and Friedman teach all the method steps as set forth above. The apparatus concerning the structure of the lysing adipose tissue device are considered inherently taught by the disclosure. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosures of Cribbs and Friedman in view of the teachings of Dory, as the pulse sequence prescribed by Dory improves the "quality of the echographic image, either of the zone to be treated or of the focal region" (Col 2, Lines 1-5). A better quality image will allow more accurate planning and more precise removal of only adipose tissue and not other undesired tissues.

9. Claims 85-100 and 185-200 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman in view of Fry, et al (US 4951653). Friedman, as previously discussed above, discloses a method for lysing adipose tissue in which a multiplicity of

target volumes are used (figure 10) such that adipose cells are removed within a subcutaneous tissue region while minimizing damage to neighboring tissues, therefore generally not lysing all other tissue except for the targeted adipose tissue (Col 2, Lines 49-59).

10. For those limitations not previously discussed, Friedman also discloses that the focused ultrasonic energy may be directed at multiple targets simultaneously, which therefore at least partially overlap in time. Phase shifting may be used to control a focal distance, which determines depth of penetration (Col 9, lines 61-63 and figure 9). A target region is chosen by selecting only the desired adipose tissue and not neighboring tissue (abstract) where the transducer is moved in response to the extent of cell destruction caused by the transducer. This target region may be either "adipose tissue" or "non-lysed adipose tissue", which are essentially the same, as "non-lysed adipose tissue" is simply adipose tissue that has not yet been treated. It is not possible to detect "lysed adipose tissue", as those cells are dead cells that have been removed by the treatment. However, Friedman does not explicitly disclose using spatial indications to define a region of interest or using computerized tracking of target volumes. Fry also discloses an ultrasonic therapy system in which Lesions in tissues are produced (abstract).

11. In addition, Fry teaches that spatial coordinate landmarks may be fixed to the body to serve as reference landmarks (Col 2, Lines 46-55). This allows for computerized tracking of the focal position that provides a fixed position relative to the tumor or other tissue. Fry states that although the system is designed for the brain, it

can "be used in the transcutaneous mode to produce lesions and other appropriate body tissues" (Col 10, Lines 4-6). Multiple lesions may be used in which the "spacing of individual Lesions to give the desired overlap in tissue boundary patterns" (Col 9, Lines 41-42). A visualization system may be used which may be ultrasonic imaging (Col 1, line 14). Visualization data is digitized, in which either pixels or voxels, depending on if the visualization is in 2D or 3D, are inherently unit volumes. Friedman and Fry teach all the method steps as set forth above.

12. The apparatus concerning the structure of the lysing adipose tissue device are considered inherently taught by the disclosure. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Friedman with the teachings of the reference by Fry as Fry states "one object of the present invention is to provide an improved method and apparatus for generating volume lesions" (Col 2, Lines 60-62) which may be used in "other appropriate body tissues" (Col 10, Line 6) besides the brain.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML 9/19/06



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